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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/911,132  | 07/23/2001  | Rainer Mueller       | RDID0073US          | 2393             |
| 23690   | 7590        | 08/09/2004           | EXAMINER            |                  |
| Roche Diagnostics Corporation<br>9115 Hague Road<br>PO Box 50457<br>Indianapolis, IN 46250-0457 |             |                      |                     | MARVICH, MARIA   |
|   |             | ART UNIT             |                     | PAPER NUMBER     |
|   |             | 1636                 |                     |                  |

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

*GM*

## Office Action Summary

|                      |                |  |
|----------------------|----------------|--|
| Application No.      | Applicant(s)   |  |
| 09/911,132           | MUELLER ET AL. |  |
| Examiner             | Art Unit       |  |
| Maria B Marvich, PhD | 1636           |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 18 May 2004.  
2a) This action is FINAL.      2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 6,7,16 and 19-23 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) 6 and 7 is/are allowed.  
6) Claim(s) 16 and 19-23 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on 07 February 2002 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

**DETAILED ACTION**

This office action is in response to an amendment filed 5/18/04. Claims 1-5, 8-15 and 17-18 have been cancelled. Claims 6-7, 16, 19-23 have been amended. Claims 6-7, 16 and 19-23 are pending in the application.

***Response to Amendment***

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are no new grounds of rejection herein that were not necessitated by applicants' amendment and therefore, this action is final.

***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on July 25, 2000. It is noted, however, that applicant has not filed a certified copy of the 100 36 491.8 application as required by 35 U.S.C. 119(b).

***Claim Objections***

Claim 16 step (c) is objected to because of the following informalities: applicants have deleted only a part of the term "a resistance gene". The word "gene" has not been deleted causing the claim to recite "comprising gene the first marker". Appropriate correction is required.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants' amendment.**

The limitation that “antibiotic is used that is higher than that used for selection of transformants that have incorporated a single copy of the alkaline phosphatase gene” has been added. Applicant has not indicated where support for this limitation is found. The specification teaches that cells are transformed and selective growth pressure is applied such that cells that have incorporated several copies of Zeocin could grow (see page 22, last paragraph). The examiner has been unable to find literal support in the originally filed specification for the limitation “antibiotic is used that is higher than that used for selection of transformants that have incorporated a single copy of the alkaline phosphatase gene”. Therefore, the limitation that “antibiotic is used that is higher than that used for selection of transformants that have incorporated a single copy of the alkaline phosphatase gene” is impermissible NEW MATTER.

Claims 16 and 19-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record in the office action mailed 9/10/03.**

The instant invention reads on eukaryotic alkaline phosphatase genes comprising SEQ ID NO:1 or SEQ ID NO:5.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

In the instant case, applicants claim a vector comprising an alkaline phosphatase gene. Applicants disclose that SEQ ID NO: 1 is the cDNA sequence for bovine alkaline phosphatase, bIAPII, coding sequence and SEQ ID NO: 5 is a codon-optimized version of bIAPII. However, the genomic version of any of the recited gene is not disclosed by the specification, nor does the prior art apparently disclose the entire gene. While the cDNA may be known, not the entire gene has been characterized. Because all of the components of the gene such as regulation sequences, introns, and exons must be determined empirically in order to generate the alkaline phosphatase gene, applicant claims the gene without any disclosure about its structure. The skilled artisan would not conclude that applicant was in possession of viral vector comprising the claimed genes.

***Response to Amendment***

Applicants traverse the claim rejections under 35 U.S.C. 112, first paragraph in the amendment filed 5/18/04. Applicants argue that the amendment to the claims has overcome the grounds for rejection.

Applicants' arguments filed 5/18/04 have been fully considered but they are not persuasive. Claims 16 and 19-23 recite alkaline phosphatase genes comprising the sequence in SEQ ID NO:1 or SEQ ID NO:5. SEQ ID NO:5 is a codon-optimized sequence and therefore the genomic version of this sequence is unknown. The cDNA for SEQ ID NO:1 is known but not all of the genomic components. In this case, the term "gene" encompasses additional elements (e.g. 5' and 3' elements associated with genomic alkaline phosphatase genes such as promoters and terminator sequences). It would be remedial to amend the claims to recite "alkaline phosphatase coding sequence" or "sequence encoding alkaline phosphatase".

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is vague and indefinite in that the metes and bounds of "yeast cells are from *Pichia pastoris* or *Hansenula polymorpha*" are unclear. By recitation of "from", it

is unclear if the cells are actually *Pichia pastoris* or *Hansenula polymorpha* or are “from” these cells. **This is a new rejection necessitated by amendment.**

***Conclusion***

Claims 6 and 7 are allowed.

Claims 16 and 19-23 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**GERRY LEFFERS** Marja B Marvich, PhD  
**PRIMARY EXAMINER** Examiner  
Art Unit 1636

August 2, 2004